U.S.S.N. 10/782,750
Filed: February 19, 2004
AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

1. (currently amended) A method for making a cell-matrix construct for use as a heart valve comprising

implanting into an animal a cell-matrix construct comprising a fibrous matrix in the shape of a heart valve or heart valve leaflet, wherein the matrix is formed of a biocompatible, biodegradable polymer having seeded therein cells selected from the group consisting of endothelial cells, myofibroblasts, skeletal muscle cells, vascular smooth muscle cells, myocytes, fibromyoblasts, and ectodermal cells, wherein the cell-matrix construct can withstand repeated stress and strain.

- 2. (currently amended) The method of claim 1 further comprising seeding wherein the matrix is seeded with dissociated parenchymal or connective tissue cells.
- 3. (previously presented) The method of claim 1 wherein the matrix is first cultured at a first site in a patient prior to being transplanted to a second site.
- 4. (previously presented) The method of claim 1 wherein the matrix is in the form of a heart valve leaflet.
- 5. (currently amended) The method of claim 1 wherein the cell-matrix construct is seeded with vascular smooth muscle cells and endothelial cells and implanted to form a heart valve.
 - 6. (cancelled)
 - 7. (cancelled)
- 8. (currently amended) The method of claim 5 wherein the <u>heart</u> valve has mechanical strength, and flexibility or pliability.

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- 9. (previously presented) The method of claim 1 wherein the cell-matrix construct is formed of a polymer selected from the group consisting of poly(lactide) (PLA), poly(glycolic acid) (PGA), poly(lactide-co-glycolide) (PLGA), poly(caprolactone), polycarbonates, polyamides, polyamhydrides, polyamino acids, polyortho esters, polyacetals, polycyanoacrylates, and degradable polyurethanes.
- 10. (previously presented) The method of claim 1 wherein the cell-matrix construct is formed of a polymer selected from the group consisting of polyacrylates, ethylene-vinyl acetate polymers, acyl substituted cellulose acetates, non-erodible polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonated polyolifins, polyethylene oxide, polyvinyl alcohol, and nylon.
- 11. (previously presented) The method of claim 1 wherein the cell-matrix construct contains interconnected pores in the range of between approximately 100 and 300 microns.
- 12. (previously presented) The method of claim 1 wherein the cell-matrix construct includes growth factors.
- 13. (previously presented) The method of claim 12 wherein the growth factors are selected from the group consisting of heparin binding growth factor (hbgf), transforming growth factor alpha or beta (TGF), alpha fibroblastic growth factor (FGF), epidermal growth factor (TGF), vascular endothelium growth factor (VEGF), insulin, glucagon, estrogen, nerve growth factor (NGF) and muscle morphogenic factor (MMP).
- 14. (previously presented) The method of claim 1 wherein the cell-matrix further comprises bioactive factors incorporated to between one and 30% by weight.
 - 15. (currently amended) The cell-matrix construct of any one of claims 1-14.
 - 16. (new) A cell-matrix construct for use as a heart valve or heart valve leaflet

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a fibrous polymeric matrix in the shape of a heart valve or heart valve leaflet, wherein the matrix is formed of a biocompatible, biodegradable polymer having seeded thereon cells comprising myofibroblasts grown to confluence and then endothelial cells seeded thereon.

17. (new) The cell-matrix construct of claim 16 wherein the cell-matrix construct can withstand repeated stress and strain.